



# UNITED STATES PATENT AND TRADEMARK OFFICE

1.

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,567	03/07/2002	Jonathan P. Wong	NEL-006	7851
23353 7590 09/21/2007 RADER FISHMAN & GRAUER PLLC LION BUILDING 1233 20TH STREET N.W., SUITE 501 WASHINGTON, DC 20036			EXAMINER HILL, MYRON G	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/091,567	<b>Applicant(s)</b> WONG ET AL.	
	<b>Examiner</b> Myron G. Hill	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This action is in response to papers filed 6/22/07.

Claims 20-32 are under consideration.

### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that based on the specification, one skilled in the art can practice the full scope of the invention. Applicant points out 2164.01(a). Applicant argues that encapsulated pCI-HA10 protected intranasally, and naked and encapsulated protected intramuscularly, that there is a reasonable correlation between activity and asserted use, that Sha et al does not teach the same lipid formation, that the instant invention is encapsulating the plasmid, not complexing with it.

Applicant's arguments have been fully considered and not found persuasive.

Applicant's claims are not commensurate in scope with the examples referred to.

Applicant argued in the response filed 7/29/05 about the difference between encapsulated and complexed. The differences are not clear and not reflected by the claims. As argued by applicant in that response, the DOSPER complexes the plasmid by charge interaction (7/29/05, page 6, bottom). The anionic charged lipids will surround the plasmid as they form complexes to cover the negatively charged DNA. The DNA is surrounded or encapsulated because it is all covered up. Both the DOSPER (and similar lipids) and the lipids of the invention are admixed with plasmid to form the lipid/plasmid composition. Applicant is not arguing that the instant lipids are not anionic.

While the specification is considered in the evaluation of the claims, the claims are considered for enablement as determined by the language of the claims. As far as the "long lasting" applicant has not provided any evidence that shows this feature or establishes a baseline for it's determination. The experiments show protection, not "long lasting" protection. Page 16 of the specification as quoted by applicant, does not refer to "long lasting" protection.

Thus, the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

Claims 20-27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.* in view of Sha *et al.* and Promega Catalog.

The invention is drawn to a liposomal plasmid influenza vaccine.

Claims 20 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler *et al.*, Webb *et al.*, Yau-Young, and Davis *et al.* in view of Sha *et al.*

The invention is drawn to a formulation of liposome for making plasmid influenza vaccine and a method of making the liposomes.

Applicant argues both rejections together.

Applicant argues that the invention is encapsulated and additionally that there is no motivation to combine the teachings. Applicant argues that Davis *et al.* teach away and it is improper under USA case law to combine references that teach way from the invention. Applicant also argues that Webb *et al.* teach oncology and cancer therapy.

Applicant's arguments have been fully considered and not found persuasive.

As discussed above the difference between complexed and encapsulated is not clear and is not reflected in the claims.

Applicant's argument that Davis *et al.* teaches away is not persuasive because the portion cited clearly says plasmids and the delivery method of liposomes. While Davis *et al.* do teach other formulations, the cited passage is descriptive of plasmids used as vaccines.

Applicant's argument that Webb *et al.* are not relevant is not persuasive because Webb *et al.* is used to teach ceramides, not cancer therapy. Wheeler *et al.* use cermides in formulations DNA for transfection and Webb *et al.* shows that different carbon chain lengths have different effects.

Thus, the rejections are maintained.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MH

Patent Examiner

10 September 2007

/Bruce Campell/

Supervisory Patent Examiner

Art Unit 1648